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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/955,248	09/17/2001	Leo Martis	DI-4641 CONT	8992

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EXAMINER

KEYS, ROSALYND ANN

ART UNIT	PAPER NUMBER
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1621

DATE MAILED: 01/14/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/955,248

Applicant(s)

MARTIS ET AL.

Examiner

Rosalynd Keys

Art Unit

1621

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 October 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of Claims

1. Claims 1-16 are pending.

Claims 1-16 are rejected.

Information Disclosure Statement

2. The information disclosure statement filed October 28, 2002 has been considered .

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Schambye et al. (Peritoneal Dialysis International, Vol. 13, Supplemental 2, October 1992, pp. S116-S118) in view of Zander (US Patent No. 5,296,242), for the reasons given in the previous office action, Paper No. 9.
5. Claims 1, 2, and 4-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Veech (US 4,663,166) in view of Zander (US Patent No. 5,296,242), for the reasons given in the previous office action, Paper No. 9.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schambye et al. (Peritoneal Dialysis International, Vol. 13, Supplemental 2, October 1992, pp. S116-S118) in view of Zander (US Patent No. 5,296,242), for the reasons given in the previous office action, Paper No. 9.

9. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech et al. (US 4,663,166) in view of Zander (U.S. Patent No. 5,296,242), for the reasons given in the previous office action, Paper No. 9.

10. Claims 1-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (US 6,020,007) in view of Zander (US 5,296,242), for the reasons given in the previous office action, Paper No. 9.

Response to Arguments

Rejection of claims 1, 2, and 4-8 under 35 U.S.C. 102(b) as being anticipated by Schambye et al. (Peritoneal Dialysis International, Vol. 13, Supplemental 2, October

Art Unit: 1621

1992, pp. S116-S118) in view of Zander (US Patent No. 5,296,242) and claims 1, 2, and 4-8 under 35 U.S.C. 102(b) as being anticipated by Veech (US 4,663,166) in view of Zander (US Patent No. 5,296,242)

11. Applicant's arguments filed October 28, 2002 have been fully considered but they are not persuasive.

Applicants argue that as a matter of law, anticipation requires the disclosure in a *single (emphasis added)* prior art reference of each element of the claim under consideration. This argument is not persuasive because normally, only one reference should be used in making a rejection under 35 U.S.C. 102. However, a 35 U.S.C. 102 rejection over multiple references has been held to be proper when the extra references are cited to:

- (A) Prove the primary reference contains an "enabled disclosure;"
- (B) Explain the meaning of a term used in the primary reference; or
- (C) Show that a characteristic not disclosed in the reference is inherent.

In the instant case multiple references are being used to show that a characteristic not disclosed in the reference is inherent. In particular, Zander is combined with Schambye et al. to show that the claimed carbon dioxide partial pressure is inherently taught by Schambye et al.

The Applicants further argue that even if the anticipation rejections are not considered improper as a matter of law, applicants respectfully submit that the cited references fail to disclose a number of features of the claimed invention. The Examiner

Art Unit: 1621

disagrees. The cited references do teach each and every element of the claimed invention, which is pointed out in the previous office action, Paper No. 9.

For the above reasons, the rejection of claims 1, 2, and 4-8 under 35 U.S.C. 102(b) as being anticipated by Schambye et al. in view of and the rejection of claims 1, 2, and 4-8 under 35 U.S.C. 102(b) as being anticipated by Veech in view of Zander are maintained.

Rejection of claims 1- under 35 U.S.C. 103(a) as being unpatentable over Schambye et al. (Peritoneal Dialysis International, Vol. 13, Supplemental 2, October 1992, pp. S116-S118) in view of Zander (US Patent No. 5,296,242; Rejection of claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Veech et al. (US 4,663,166) in view of Zander (U.S. Patent No. 5,296,242; and rejection of claims 1-16 under 35 U.S.C. 103(a) as being unpatentable over Veech (US 6,020,007) in view of Zander (US 5,296,242

The Applicants argue that the primary references are clearly deficient with respect to the claimed invention. The Examiner disagrees for reasons given in the previous office actions.

The bulk of the Applicants' arguments are directed to the Zander reference. The applicants argue that while Zander does teach a dialysis solution with a carbon dioxide partial pressure of about 40 mmHg, a person skilled in the art of peritoneal dialysis would readily recognize that the solutions proposed by Zander would not be effective in maintaining the acid-base balance of dialysis patients. This argument is not persuasive because 1) it is not the solution of Zander that the instant claims are found

Art Unit: 1621

to be unpatentable, but the solution that results as a combination of the primary references with the carbon dioxide partial pressure disclosed by Zander (see previous office action, Paper No. 9); and 2) Zander teaches that by using carbon dioxide partial pressures that correspond to physiological blood plasma (40 mm Hg) one can prevent alkalosis or acidosis from occurring (see column 2, lines 35-54).

With regard to the Applicants arguments that the preferred weak acid of Zander is clearly acetic acid/acetate, the Examiner wishes to remind the applicants that it is well established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches to a person of ordinary skill in the art. In re Boer, 355 F.2d 961, 148 USPQ 507 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983). In the instant case, Zander clearly suggests the use of other weak acids, including the claimed weak acids, which are also taught by the primary references.

Any further arguments with regard to Zander teaching the use of acetic acid/acetate will not be addressed by the Examiner because the rejection is not based on the use of acetic acid/acetate as taught by Zander, but on the combination of Zander with the primary references, as mentioned above. It is this combination of references that the applicants' invention has failed to patentably distinguish over. Further, it has been held that one cannot show non-obviousness by attacking references individually

Art Unit: 1621

where, as here, the rejections are based on combinations of references. In re Keller, 208 USPQ 871 (CCPA 1981).

In response to Applicants' arguments that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the invention was made, and does not include knowledge gleaned only from the applicants' disclosure, such a reconstruction is proper. In re McLaughlin, 443 F.2d 1392; 170 USPQ 209 (CCPA 1971). In the instant case, all elements of the claimed invention are disclosed by the cited references. There is no element or part of Applicants' claimed invention, which is not suggested or specifically disclosed. The motivation to combine the teaching of the references is found in column 2, lines 35-54 of Zander.

The Applicants' argue that the Examiner's conclusion of obviousness is based upon an "obvious to try" rationale. The Examiner disagrees because the cited references disclose the use of each of the claimed elements in a peritoneal dialysis solution as well as the reason or motivation for using the claimed amounts of each of the elements.

The Applicants' argue that Zander teaches away from its combination with the cited primary references. The Examiner disagrees. In column 3, lines 62-68 Zander teaches that the inventive solutions contain the immediate buffer bicarbonate in physiological concentration, together with the long-term buffer metabolized anion in the

Art Unit: 1621

desired concentration. Preferred metabolizable acids useable in the aqueous solutions according to the invention are pyruvic, lactic, oxalic, fumaric, acetic, malic, maleic, malonic and succinic acids. The solution disclosed in Schambye et al. contain bicarbonate and lactate. The solutions disclosed in Veech '166 and Veech '007 contain bicarbonate with pyruvate and/or lactate. Thus, the possible dialysis solutions disclosed by Zander correspond to the dialysis solutions, which are disclosed by the primary references. What is lacking in the primary references is a specific teaching to use physiological carbon dioxide partial pressures, i.e., a carbon dioxide partial pressure of 40 mmHg. Zander teaches using a physiological carbon dioxide partial pressure. The reason to use such pressure has been given above, as well as in the previous office action, Paper No. 9.

The Examiner believes a prima facie case of obviousness has been shown. Thus, for the above reasons the rejections under 35 USC 103(a) are maintained.

Conclusion

12. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

Art Unit: 1621

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosalynd Keys whose telephone number is 703-308-4633. The examiner can normally be reached on M and F 3:00-8:00 pm and T-R 5:30-10:30 am.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 703-308-4532. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

R. Keys

R. Keys
January 10, 2003

Rosalynd Keys

Rosalynd Keys
Primary Examiner
Art Unit 1621